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PROF. KROCZEK, RKI

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Richard KroczeK

Confirmation No.: 7620

Application No.: 09/509,283

Group Art Unit: 1644

Filed: August 11, 2000

Examiner: J. Roark

For: ANTI-HUMAN COSTIMULATING T-CELL  
POLYPEPTIDE MONOCLONAL  
ANTIBODIES

Attorney Docket No.: 7853-215

**STATEMENT OF APPLICANT REGARDING PERMANENCE  
AND AVAILABILITY OF DEPOSITED MICROORGANISMS**

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

I, Richard KroczeK, Applicant of the above-identified application, declare and state:

1. That hybridoma 8F4, secreting native monoclonal antibody 8F4, was deposited with the Deutsche Sammlung Von Mikroorganismen und Zellkulturen GmbH ("DSMZ"), at Mascheroder Weg 1b, D-3300 Braunschweig, Germany, on April 9, 2002, in compliance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure on my own behalf and on the behalf of the Bundesrepublik Deutschland, letztvertreten durch den Direktor des Robert-Koch-Institutes, having a place of business at Nordufer 20, D-13353 Berlin, Germany, present assignee of the application. The

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deposited hybridoma was assigned DSMZ accession number DSM ACC2539. A copy of the Receipt of Deposit is attached hereto as Exhibit 1.

2. That I participated in and supervised the production and maintenance of the hybridoma designated 8F4 which was deposited with the DSMZ on April 9, 2002 and assigned DSMZ accession number DSM ACC2539.

3. That I confirm and corroborate that the hybridoma 8F4 deposited on April 9, 2002 with the DSMZ and assigned DSMZ accession number DSM ACC2539, which produces the monoclonal antibody 8F4, is the same hybridoma that was described in the specification of the above-identified application in Examples 1-8 at pages 11-19.

4. I hereby assure the United States Patent and Trademark Office and the public that (a) all restrictions on the availability to the public of the hybridoma referred to in paragraph 1 will be irrevocably removed upon issuance of a United States patent making reference to the hybridoma; (b) the hybridoma will be maintained for a period of at least five years after the most recent request for the furnishing of a sample of the deposited hybridoma was received by the DSMZ and, in any case for a period of at least 30 years after the date of deposit; (c) should the deposit become non-viable it will be replaced; and (d) access to the hybridoma will be available to the Commissioner during the pendency of the patent application or to one determined by the Commissioner to be entitled to the hybridoma under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

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5. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Date

October 8, 2002R. Kroczeck

Richard Kroczeck, M.D.

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## **Exhibit 1**

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

Robert Koch-Institut  
Nordufer 20  
13353 BerlinVIABILITY STATEMENT  
Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this page

I. DEPOSITOR		II. IDENTIFICATION OF THE MICROORGANISM	
Name: Robert Koch-Institut Nordufer 20 Address: 13353 Berlin		Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  DSM ACC2539  Date of the deposit or the transfer:  2002-04-09	
III. VIABILITY STATEMENT			
The viability of the microorganism identified under II above was tested on On that date, the said microorganism was		2002-04-09	
<input checked="" type="checkbox"/> viable			
<input type="checkbox"/> no longer viable			
IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED			
V. INTERNATIONAL DEPOSITARY AUTHORITY			
Name: DSMZ-DEUTSCHE SAMMLUNG VON MIKROORGANISMEN UND ZELLKULTUREN GmbH Address: Eschenbergweg 16 D-38124 Braunschweig		Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):  U. Weh  Date: 2002-04-16	

- \* Indicate the date of original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).  
\* In the cases referred to in Rule 10.2(a) (i) and (ii), refer to the most recent viability test.  
\* Mark with a cross the applicable box.  
\* Fill in if the information has been requested and if the results of the test were negative.

Form DSMZ-BF79 (sole page) 12/2001

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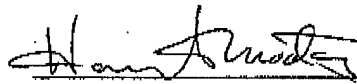
**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE  
UNITED STATE PATENT AND TRADEMARK OFFICE**

**LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)**

Dr. Abu-Shaar is hereby given limited recognition under 37 CFR §10.9(b) as an employee of Pennie & Edmonds, LLP to prepare and prosecute patent applications wherein the patent applicant is the client of Pennie & Edmonds, LLP, and the attorney or agent of record in the applications is a registered practitioner who is a member of Pennie & Edmonds, LLP. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Dr. Abu-Shaar ceases to lawfully reside in the United States, (ii) Dr. Abu-Shaar's employment with Pennie & Edmonds, LLP ceases or is terminated, or (iii) Dr. Abu-Shaar ceases to remain or reside in the United States on an H-1B visa.

This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the U.S. Patent and Trademark Office.

**Expires: May 28, 2004**



Harry I. Moatz  
Director of Enrollment and Discipline